

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

Defendant

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1 Plaintiff's motion for summary judgment should be granted.

2 More than 200 days after Plaintiff first filed her motion for summary judgment, after Mrs.  
3 Zieroth passed away and her grieving husband was forced to continue the litigation in her name,  
4 and more than 70 days after Plaintiff filed her renewed motion for summary judgment, the  
5 Secretary finally filed a seven page response to the motion.  
6

7 As set forth in Mrs. Zieroth's motion, summary judgment may be granted for Mrs.  
8 Zieroth for three independent reasons: 1) CMS 1682-R issued illegally and the Secretary is  
9 barred by statute from giving it effect (as is this Court); 2) the Secretary's construction of the  
10 phrase "primarily and customarily used to serve a medical purpose" in CMS 1682-R is legally  
11 wrong; and/or 3) a CGM is "durable medical equipment" either pursuant to the regulations or as  
12 a "blood glucose monitor" (42 U.S.C. § 1395x(n)) and the Secretary's conclusion otherwise is  
13 not supported by substantial evidence, is arbitrary and capricious, and is contrary to law.  
14

15 The Secretary does not dispute the fact the CMS 1682-R issued illegally and that, by  
16 attempting to enforce the illegally issued Ruling, the Secretary is defying Congress' mandate that  
17 no such rule, requirement, or other statement of policy "shall take effect." *See* 42 U.S.C. §  
18 1395hh. Instead, the Secretary contends that Mrs. Zieroth cannot complain that the Secretary is  
19 knowingly violating Congress' command because Mrs. Zieroth did not raise that position before  
20 the ALJ and the MAC. That position is wholly without legal basis. Under the Secretary's own  
21 regulations, both the ALJ and the Medicare Appeals Council were/are barred from determining  
22 that CMS 1682-R was/is invalid. Mrs. Zieroth was not required to engage in futile acts to  
23 preserve her right to protest the Secretary's illegal conduct. Indeed, given that CMS 1682-R  
24 issued in violation of a law issued by Congress, the Secretary's reliance on the illegally issued  
25 Ruling is also in violation of the law, and that the Secretary asks this Court to violate the statute  
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28

1 as well, Mrs. Zieroth seriously doubts that there could ever be waiver of these *ultra vires* acts.

2       Beyond the illegal issuance of CMS 1682-R, the Secretary does not contend that the  
3 phrase “primarily and customarily used to serve a medical purpose” is ambiguous. Instead, the  
4 Secretary simply offers his own unsupportable construction in the form of the “therapeutic” /  
5 “non-therapeutic” / “precautionary” terms of CMS 1682-R. That approach violates the first  
6 canon of statutory/regulatory construction – determining whether the relevant provision is  
7 ambiguous. Likewise, the Secretary does not contend that the phrases “durable medical  
8 equipment” and/or “blood glucose monitor” are ambiguous and, again, simply offers  
9 constructions that are not supportable.  
10

11       Finally, the Secretary closes with a request to remand this case so that the Secretary can  
12 have the opportunity to create new bases to deny Mrs. Zieroth’s claim. Under the Secretary’s  
13 own regulations, the Secretary cannot consider Mrs. Zieroth’s claim on any basis other than  
14 alleged misapplication of CMS 1682-R (*i.e.*, the basis on which review by the Council was  
15 granted). Thus, a remand to deny Mrs. Zieroth’s claim on any other basis would be improper.  
16

17       Mrs. Zieroth’s motion for summary judgment should be granted, the Secretary’s motion  
18 denied, and coverage ordered.

## 19                                   **I.       DISCUSSION**

20       At base, there are two main issues before this Court: 1) did CMS 1682-R issue illegally  
21 (and therefore a rejection based on it is improper); and 2) independently, is a CGM “primarily  
22 and customarily used to serve a medical purpose” / “durable medical equipment” / a “blood  
23 glucose monitor.”  
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1 **A. CMS 1682-R**

2 **1. CMS 1682-R Issued Illegally, Is Not Supported by**  
 3 **Substantial Evidence, Is Arbitrary and Capricious, Etc.**

4 The Secretary did not respond to or challenge Mrs. Zieroth's showing that CMS 1682-R  
 5 issued illegally, is not supported by substantial evidence, or is arbitrary and capricious. That is,  
 6 the Secretary did not contest that, pursuant to 42 U.S.C. § 1395hh, the Secretary was required to  
 7 comply with notice and comment, that the Secretary did not do so, and that pursuant to the  
 8 statute, the Ruling "shall [not] take effect." Mot. at 12-13.

9 Likewise, independent of the improper issuance of the Ruling, the Secretary did not  
 10 contest that the Ruling's purported construction of "primarily and customarily used to serve a  
 11 medical purpose" is not supported by substantial evidence, is arbitrary and capricious, and wrong  
 12 as a matter of law. Mot. at 13-17.

13 Thus, coverage should be ordered.

14 **2. Mrs. Zieroth Did Not Waive the Argument that**  
 15 **CMS 1682-R Issued Illegally**

16 Pursuant to 42 C.F.R. § 405.1063(b):

17 CMS Rulings are published under the authority of the Administrator, CMS.  
 18 Consistent with § 401.108 of this chapter, *rulings are binding* on all CMS  
 19 components, on all HHS components that adjudicate matters under the  
 20 jurisdiction of CMS, and on the Social Security Administration to the extent that  
 21 components of the Social Security Administration adjudicate matters under the  
 jurisdiction of CMS.

22 (emphasis added). Thus, under the Secretary's own regulations, neither ALJs nor the Medicare  
 23 Appeals Council have any authority to rule on the validity of CMS Rulings.<sup>1</sup> Indeed, citing this  
 24 same regulation in the decision at issue reversing ALJ Midgley, the Council stated: "We, like  
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26  
 27 <sup>1</sup> Indeed, 42 C.F.R. § 405.1063(a) contains a similar provision making all laws and regulations  
 28 binding on ALJs and the Council, and therefore immune to validity challenges before them.

1 ALJs, are bound by CMS Rulings.” *See* CAR13. Even the Secretary’s Opposition states: “The  
2 Appeals Council found that CMS Ruling 1682-R required [the Council] to deny coverage.” *Opp.*  
3 at 4.

4 It is fundamental that Mrs. Zieroth cannot waive arguments that both the ALJ and the  
5 Medicare Appeals Council are barred from addressing. That is, Mrs. Zieroth was not required to  
6 perform the futile act of asking either the ALJ or the Council to rule on the validity of CMS  
7 1682-R (when both entities are barred from addressing that argument) in order to avoid waiver.  
8 *See, e.g., In re Two Appeals Arising out of San Juan DuPont Plaza Hotel Fire Litigation*, 994  
9 F.2d 956, 961 (1<sup>st</sup> Cir. 1993) (“The law does not require litigants to run fools’ errands. Thus, a  
10 party who forgoes an obviously futile task will not ordinarily be held thereby to have waived  
11 substantial rights.”); *Northern Heel Corp. v. Compco Indust., Inc.*, 851 F.2d 456, 461 (1<sup>st</sup> Cir.  
12 1988) (“The law should not be construed idly to require parties to perform empty acts or to  
13 engage in empty rituals.”); *Kinslow v. American Postal Workers Union, Chicago Local*, 222 F.3d  
14 269, 276 (7<sup>th</sup> Cir. 2000) (a statutory provision “does not require a union member to perform  
15 futile acts in order to vindicate his rights.”); *Miller v. Drexel Burnham Lambert, Inc.*, 791 F.2d  
16 850, 854 (11<sup>th</sup> Cir. 1986) (“This circuit does not require a litigant to engage in futile gestures  
17 merely to avoid a claim of waiver.”).

18 Likewise, in the related context of exhaustion, the Ninth Circuit has held that prudential  
19 exhaustion is not required “if administrative remedies are inadequate or not efficacious, [or]  
20 pursuit of administrative remedies would be a futile gesture.” *See Hernandez v. Sessions*, 872  
21 F.3d 976, 988 (9<sup>th</sup> Cir. 2017). *See also Shalala v. Illinois Council on Long Term Care, Inc.*, 529  
22 U.S. 1, 13 (2000) (exhaustion not required “when exhaustion would prove futile”); *McCarthy v.*  
23 *Madigan*, 503 U.S. 140, 148 (1992) (“Alternatively, an agency may be competent to adjudicate  
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1 the issue presented, but still lack authority to grant the type of relief requested.”); *Montana Nat’l*  
 2 *Bank of Billings v. Yellowstone County, Montana*, 276 U.S. 499, 505 (1928) (no waiver because  
 3 “any such application utterly futile since the county board of equalization was powerless to grant  
 4 any appropriate relief[.]”).

5 Here, under the Secretary’s own regulations, the ALJ and the Council are bound by CMS  
 6 Rulings and cannot address the validity of them. Thus, Mrs. Zieroth could not have waived an  
 7 argument that the ALJ and Council were precluded from addressing. The first body with both  
 8 the authority to rule on the validity of CMS 1682-R and where Mrs. Zieroth has a venue to make  
 9 that challenge is this Court - where Mrs. Zieroth promptly brought her claim.<sup>2</sup>

11 That said, Mrs. Zieroth explicitly argued that a CGM is “durable medical equipment” /  
 12 “primarily and customarily used to serve a medical purpose” (*i.e.*, the very regulation that CMS  
 13 1682-R purports to construe) before the Council as well as throughout the appeal process. *See*,  
 14 *e.g.*, CAR29 (to council); CAR526 (on Reconsideration).<sup>3</sup> Having actually made that argument,  
 15 Mrs. Zieroth clearly could not have waived it. Indeed, the Secretary concedes that Mrs. Zieroth  
 16 argued that to the extent that the Ruling held that a CGM was not “durable medical equipment” it  
 17 is contrary to the statute and regulations. Opp. at 4.

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22 <sup>2</sup> Moreover, Mrs. Zieroth observes that the notice and comment provisions of 42 U.S.C. §  
 23 1395hh are not limited in their application to the Secretary. Instead, those provisions state that  
 24 no rule, requirement, or other statement of policy “shall take effect” unless promulgated in  
 25 accordance with the notice and comment requirements. That prohibition applies just as much to  
 this Court as to the Secretary. In this litigation, the Secretary is asking the Court to give effect to  
 CMS 1682-R when that is explicitly barred by statute. Thus, Mrs. Zieroth seriously doubts that  
 she could ever waive the requirements of the statute.

26 <sup>3</sup> Pursuant to 42 C.F.R. § 405.1108(a), upon review: “The Council will consider all of the  
 27 evidence in the administrative record.” Thus, in addition to Mrs. Zieroth’s arguments on  
 Reconsideration being listed among the Exhibits to ALJ Midgley’s decision (*see* CAR58), the  
 Council had those same arguments before it as part of the Record below.

### 3. The Secretary Waived a Waiver Defense

Pursuant to FED.R.CIV.P. 8(c)(1), “In responding to a pleading, a party must affirmatively state any avoidance or affirmative defense, including: ... waiver.” As set forth in the Complaint, Mrs. Zieroth alleged that CMS 1682-R issued in violation of the law and that the denial of her claim on that basis was also improper. *See, e.g.*, Dkt. #21 at 9, 10, 17. On May 1, 2020, the Secretary filed his Answer and did not assert waiver as a defense. *See* Dkt. #22. Thus, pursuant to the Federal Rules, the Secretary waived a waiver defense.

Despite the text of the Federal Rules, the Ninth Circuit has held that a defendant who fails to raise an affirmative defense in a responsive pleading will still be allowed to raise the defense if it can show that the plaintiff was not prejudiced by the delay. *See Magana v. Commonwealth of the Northern Mariana Islands*, 107 F.3d 1436, 1446 (9<sup>th</sup> Cir. 1997). Here, the Secretary made no effort to demonstrate that his delay did not prejudice Mrs. Zieroth. Thus, on that basis alone, the Secretary failed to meet his burden and waived a waiver defense.

Moreover, the Secretary could simply never show that his failure to raise the defense did not prejudice Mrs. Zieroth and her grieving husband. As indicated, the first Mrs. Zieroth’s representative heard of an alleged waiver defense was:

- a) more than 200 days *after* the initial motion for summary judgment was filed;
- b) *after* Mrs. Zieroth actually passed away;
- c) more than 70 days *after* the renewed motion for summary judgment was filed;
- d) *after* the Secretary moved for a 90-day extension of time to oppose the motion for summary judgment on the grounds that something the Secretary was going to do would effect/obviate the arguments on the motion for summary judgment;

e) *after* Mrs. Zieroth opposed the Secretary's motion without knowing that the Secretary intended to assert a waiver defense that would not be effected by subsequent developments; and

f) *after* this Court granted the Secretary a 45-day extension to oppose the motion for summary judgment without knowing of the alleged waiver defense that would not be effected by subsequent developments.

In somewhat similar circumstances, another court in this district held that the failure to comply with FED.R.CIV.P. 8(c) resulted in waiver as a result of prejudice to the plaintiff. *See Jorst v. D'Ambrosio Brothers*, 2001 WL 969039 at \*9 (N.D. Cal. Aug. 13, 2001) (Breyer, J.) (plaintiff would be prejudiced when waiver defense raised after, *inter alia*, summary judgment motion prepared).

The Secretary waived any waiver defense and coverage should be ordered.

## **B. A CGM Is "Durable Medical Equipment"**

Coverage in this case should also be ordered because a CGM meets the regulatory requirement of being "primarily and customarily used to serve a medical purpose" and/or the statutory requirements of "durable medical equipment" / "blood glucose monitor." Further, the Secretary's new rationale for denying coverage must be rejected as it was not the rationale used by the Council to deny coverage.

### **1. A CGM Is "Primarily and Customarily Used to Serve a Medical Purpose"**

As set forth in the Council's decision denying coverage and Mrs. Zieroth's opening papers, the Council denied Mrs. Zieroth's claim on the grounds that a CGM is not covered "durable medical equipment" because it does not meet the regulatory requirement of being "primarily and customarily used to serve a medical purpose." *See* 42 C.F.R. § 410.202; CAR11

1 (“We begin our analysis with the principle underlying CMS’ treatment of CGMs, *i.e.*, that, DME  
2 must be ‘primarily and customarily used to serve a medical purpose.’”). Relying on the  
3 construction of the “primarily and customarily ...” phrase set forth in CMS 1682-R, the Council  
4 denied Mrs. Zieroth’s claim.

5  
6 As noted in Mrs. Zieroth’s papers, the first step in regulatory construction is to determine  
7 whether the provision is ambiguous and the phrase “primarily and customarily used to serve a  
8 medical purpose” is not ambiguous. *See, e.g.*, Mot. at 7-8, 15. Moreover, the Secretary’s  
9 opposition does not assert that the phrase is ambiguous. Thus, as stated in the Supreme Court’s  
10 decision in *Kisor v. Wilkie*, 139 S.Ct. 2400, 2415-6 (2019) - “If uncertainty does not exist, then  
11 there is no plausible reason for deference. The regulation just means what it means – and the  
12 court must give it effect, as the court would any law.” Moreover, if a provision is not  
13 ambiguous, deferring to any proposed construction by the agency “would permit the agency,  
14 under the guise of interpreting a regulation, to create a *de facto* new regulation.” *Id.*

15  
16 Given the lack of ambiguity in the relevant phrase, the only issue is whether there is  
17 substantial evidence to support the Council’s conclusion that a CGM is not “primarily and  
18 customarily used to serve a medical purpose.” Of course, there is no evidence (much less  
19 substantial evidence) to support that conclusion. No amount of sophistry or obfuscation can  
20 change the fact that a CGM has *only* a medical purpose (and an important one at that).

21  
22 Likewise, the Secretary’s decision that a CGM is not “primarily and customarily used to  
23 serve a medical purpose” is arbitrary and capricious. That is, that conclusion “runs counter to the  
24 evidence before the agency, [and/or] is so implausible that it could not be ascribed to a difference  
25 in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm*  
26 *Mutual Automobile Ins. Co.*, 436 U.S. 29, 43 (1983).

1 Accordingly, coverage should be ordered.

2 **2. A CGM Is “Durable Medical Equipment” / a “Blood Glucose Monitor”**

3 For the same reasons that the Secretary’s position regarding “primarily and customarily  
4 used to serve a medical purpose” is wrong, the Secretary’s claim that a CGM is not “durable  
5 medical equipment” and/or a “blood glucose monitor” is also wrong. In each case, the Secretary  
6 failed to perform the first step of statutory construction – determining if the statute is ambiguous  
7 – and does not contend that the statute is ambiguous. Thus, under the plain meaning of those  
8 phrases a CGM is “durable medical equipment” / a “blood glucose monitor” and there is not  
9 substantial evidence to support the Secretary’s claim otherwise, the Secretary’s position is  
10 arbitrary and capricious, etc.

12 Indeed, with regard to “blood glucose monitor”, the Secretary concedes that a CGM  
13 measures something correlated with blood glucose<sup>4</sup> and, thereby, indirectly measures blood  
14 glucose itself. Opp. at 6. As Mrs. Zieroth noted in her opening papers, there is no basis for  
15 changing the statutory phrase of “blood glucose monitor” to “*direct* blood glucose monitor.” In  
16 addition to the above, in light of the Secretary’s concession, there is no basis to conclude that a  
17 CGM is anything other than a “blood glucose monitor” within the meaning of 42 U.S.C. §  
18 1395x(n) and coverage should be ordered.

20 **3. The Secretary’s New Rationales For Denying Coverage Must Be Rejected**

21 The Secretary’s opposition offers a rationale for denying Mrs. Zieroth’s claim that is not  
22 the basis of the Council decision being appealed. The Council decision denying Mrs. Zieroth’s  
23 claim was founded on the allegation that a CGM is not “primarily and customarily used to serve  
24 a medical purpose” because it does not meet the construction of that phrase set forth in CMS  
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27 <sup>4</sup> That is, glucose coming from the blood on the way to the cells in the “interstitial fluid.”  
28

1 1682-R. CAR11-13. By contrast, the Secretary’s opposition asserts that Mrs. Zieroth’s CGM  
2 should not be covered because it is allegedly not as accurate as other devices. Opp. at 5-7. That  
3 is a different rationale than that offered by the Council.

4 “It is well-established that an agency’s action must be upheld, if at all, on the basis  
5 articulated by the agency.” *State Farm*, 436 U.S. at 50; *Snoqualmie Indian Tribe v. F.E.R.C.*,  
6 545 F.3d 1207, 1212 (9<sup>th</sup> Cir. 2008) (“An agency’s decision can be upheld only on the basis of  
7 the reasoning in that decision.”); *Doe v. Wolf*, 2020 WL 3128874 at \*7 (N.D. Cal. June 12, 2020)  
8 (Ryu, J.) (“Defendants’ positions suffer from a fatal flaw: they are being raised for the first time  
9 in this lawsuit, and do not reflect the reasoning provided by the agency in the first instance.”).  
10 Thus, the Secretary’s post-hoc rationalization for denying Mrs. Zieroth’s claim should be  
11 rejected.  
12

13 Even so, the Secretary’s new position is still without merit. Simply put, alleged accuracy  
14 has nothing to do with whether a device is “durable medical equipment”, is “primarily and  
15 customarily used to serve a medical purpose”, and/or is a “blood glucose monitor.” By way of  
16 example, the scale in your bathroom may be less accurate than the one at the doctor’s office.  
17 Nevertheless, they are still both “scales” and “primarily and customarily used” to measure  
18 weight. Likewise, that a finger stick is allegedly more accurate than a CGM, does not make a  
19 CGM less durable or used for some purpose other than a medical one.  
20

### 21 **C. Coverage Should Be Ordered**

22 As noted in Mrs. Zieroth’s motion for summary judgment and reflected in the Record, the  
23 Secretary (in the form of his representative – the Center for Medicare and Medicaid Services  
24 (CMS)) chose not to participate in the hearings held by ALJ Midgley on the claims at issue.  
25  
26  
27  
28

1 Mot. at 5; CAR1679, CAR867, CAR048. Thereafter, ALJ Midgley ruled in Mrs. Zieroth's  
2 favor.

3 Pursuant to the Secretary's own regulations, in such a situation, the Council may review  
4 an appeal on so-called "own motion review" but:

5 The Council will accept review if the decision or dismissal contains an error of  
6 law material to the outcome of the case or presents a broad policy or procedural  
7 issue that may affect the general public interest. In deciding whether to accept  
8 review, *the Council will limit its consideration of the ALJ's or attorney*  
*adjudicator's action to those exceptions raised by CMS.*

9 See 42 C.F.R. § 405.1110(c)(2) (emphasis added). As noted in Mrs. Zieroth's motion for  
10 summary judgment, the "exceptions" raised by CMS were limited to the alleged misapplication  
11 of CMS 1682-R and no other reason. Mot. at 5; CAR38-47. Thus, pursuant to 42 C.F.R. §  
12 405.1110(c)(2), Council review was, and is, limited to the alleged misapplication of CMS 1682-  
13 R.  
14

15 If this Court determines that either CMS 1682-R issued improperly (and, therefore that a  
16 rejection based on it was improper) or that the idea that a CGM is not "primarily and customarily  
17 used to serve a medical purpose" / "durable medical equipment" / a "blood glucose monitor" is  
18 not supported by substantial evidence, is arbitrary and capricious, etc., on remand it would be  
19 improper for the Council to consider any basis for rejecting Mrs. Zieroth's claim. That is, it  
20 would violate 42 C.F.R. § 405.1110(c)(2) for the Council to consider any other grounds for  
21 rejecting Mrs. Zieroth's claim. Accordingly, Mrs. Zieroth's claim would have to be granted and  
22 a remand for any substantive consideration would be an act of futility. Pursuant to 42 U.S.C. §  
23 405(g) (fourth sentence), coverage should simply be ordered.  
24

25 The Secretary's request for a remand "so that the Secretary can decide Mrs. Zieroth's  
26 claim without reference to the disputed Ruling" (Opp. at 5) is simply a request that the Secretary  
27 be given a chance to violate his own regulations and needlessly prolong the litigation. Clearly,  
28

1 that would be improper and remanding when the result is dictated would be needless and futile.  
 2 Indeed, this is not the first Court to consider (and reject) the Secretary’s request for a remand so  
 3 that the Secretary has an opportunity to violate his own regulations. *See Maupin v. Azar*, 424  
 4 F.Supp.3d 830, 838-39 (C.D. Cal. 2019) (Fitzgerald, J.) (refusing to remand for substantive  
 5 consideration when appeal to Council was on limited grounds that were reversed). *See also*  
 6 *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n. 6 (1969) (“To remand would be an idle  
 7 and useless formality. *Chenery* does not require that we convert judicial review of agency action  
 8 into a ping-pong game.”).

10 Because CMS’ referral was limited to the issue of alleged improper application of CMS  
 11 1682-R, if this Court grants Mrs. Zieroth’s motion substantively, pursuant to 42 U.S.C. § 405(g)  
 12 (fourth sentence), a substantive remand would be futile. Accordingly, coverage should be  
 13 ordered and this matter remanded to the Secretary solely for payment.  
 14

## 15 II. CONCLUSION

16 For the reasons set forth above, this Court grant summary judgment that CMS 1682-R  
 17 issued in violation of law and that, therefore, reliance on it to reject Mrs. Zieroth’s claim was  
 18 improper. In addition or in the alternative, this Court should grant summary judgment that a  
 19 CGM is covered “durable medical equipment” because it is “primarily and customarily used to  
 20 serve a medical purpose”, a “blood glucose monitor”, and/or simply “durable medical  
 21 equipment.” For any and for all of these reasons, the Court should order coverage and remand to  
 22 the Secretary with instruction to pay Mrs. Zieroth’s claim.  
 23

24  
 25 Dated: August 10, 2020

Respectfully submitted,

27 PARRISH LAW OFFICES

/s/ James C. Pistorino

James C. Pistorino

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